COMMERCE DEPARTMENT

Evaluation of HF 4899: Requirement for Health Plans to Provide Coverage for Biomarker Testing

Report to the Minnesota Legislature Pursuant to Minn. Stat. § 62J.26

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Defrayal analysis completed by the Minnesota Department of Commerce is independent of AIR's evaluation.

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Contents

Executive Summary 1

Introduction 3
- Evaluation Components 3

Bill Requirements 4

Related Health Conditions 4

Related State and Federal Laws 5
- Federal Laws Relevant to the Proposed Mandate 5
- Minnesota State Laws Relevant to the Proposed Mandate 5
- State Comparison 5

Public Comments Summary 6
- Stakeholder Engagement Analysis 6

Evaluation of Mandated Health Benefit Proposal 8
- Public Health Impact 9
- Economic Impact 10
- Fiscal Impact 19

Appendix A. Bill Text 21

Appendix B. Key Search Terms for Literature Scan 23

Appendix C. Associated Codes 24

Executive Summary

This proposed mandate would require health plans to cover biomarker tests to diagnose, treat, manage, and monitor illness or disease when the testing is supported by medical evidence. “Biomarker" refers to a characteristic that can be objectively measured and evaluated as an indicator of normal biological processes, disease processes, or responses to a specific therapy.

Evidence suggests that biomarker testing can optimize treatment by helping to assess the potential risks or effectiveness of certain drugs based on individual biomarkers. Research also suggests that biomarker testing may reduce adverse outcomes and help health care providers select the most appropriate drug for a patient. However, even though evidence exists to support the use of certain biomarker tests, health insurance coverage for biomarker tests varies, and those variations are not always based on clinical practice guidelines.

Data demonstrating a link between insurance coverage of biomarker testing and improved clinical outcomes are currently limited. One study found that patients who did not have access to biomarker testing had a 27% increased risk of mortality compared with those that did have such access. However, more research is needed in this area. While there is evidence showing that certain biomarker tests are clinically useful, some providers have expressed uncertainty about their ability to interpret biomarker test results and incorporate them into clinical practice.

Some data suggest that medically necessary biomarker testing may be cost-effective and that cost-effectiveness may vary by biomarker test, the timing of testing, and other variables. Proactive testing (testing prior to indicated use) could reduce downstream costs of care compared to reactive testing (testing once a suspected need has been established).

The additional costs of this mandate will depend on the how many biomarker tests are supported by clinical evidence and how widely they are used. For the non-public insured population, the average monthly expenditures are projected to increase between $0.09 and $0.22 per member in Year 1 and between $0.14 and $0.32 per member in Year 10. On average, an increase of about 1.2 tests per 1,000 individuals would increase monthly premiums by only $0.01 per member. Due to the limited data on the numerous biomarker tests currently available, a comprehensive actuarial analysis and modeling of projected downstream medical savings resulting from increased coverage of biomarker testing was beyond the scope of this project.

The potential fiscal impact of this mandate is as follows:

- The State Employee Group Insurance Program (SEGIP) estimated that the partial fiscal impact of this legislation would be $116,100 in Fiscal Year 2023 (FY23) and $243,810 in FY24.

- Commerce has determined that this proposed mandate would likely require partial defrayal under the Affordable Care Act up to $2,594,000 in the first year.
- There is no estimated cost for public programs, as the state insurance mandate only applies to non-public, fully insured small and large group plans and to SEGIP, unless explicitly indicated otherwise.

Pursuant to Minn. Stat. § 62J.26, subd. 3, the Minnesota Department of Commerce (Commerce) is required to perform an evaluation of the first engrossment of House File 4899 on health insurance coverage for biomarker testing from the 92nd Legislature (2021–2022). The purpose of the evaluation is to provide the legislature with a detailed analysis of the potential impacts of any mandated health benefit proposal.

House File 4899 meets the definition of a mandated health benefit proposal under Minn. Stat. § 62J.26, which indicates the following criteria:

A “mandated health benefit proposal" or "proposal" means a proposal that would statutorily require a health plan company to do the following:

(i) provide coverage or increase the amount of coverage for the treatment of a particular disease, condition, or other health care need;

(ii) provide coverage or increase the amount of coverage of a particular type of health care treatment or service or of equipment, supplies, or drugs used in connection with a health care treatment or service;

(iii) provide coverage for care delivered by a specific type of provider;

(iv) require a particular benefit design or impose conditions on cost-sharing for:

(A) the treatment of a particular disease, condition, or other health care need;

(B) a particular type of health care treatment or service; or

(C) the provision of medical equipment, supplies, or a prescription drug used in connection with treating a particular disease, condition, or other health care need; or

(v) impose limits or conditions on a contract between a health plan company and a health care provider.

"Mandated health benefit proposal" does not include health benefit proposals amending the scope of practice of a licensed health care professional.

Introduction

In accordance with § 62J.26, Commerce performs, in consultation with the Minnesota Department of Health (MDH) and Minnesota Management and Budget (MMB), a detailed evaluation of all relevant benefit mandate proposals.

a. Evaluations must focus on the following areas:
    i. Scientific and medical information regarding the proposal, including the potential for benefit and harm
    ii. Overall public health and economic impact
    iii. Background on the extent to which services/items in the proposal are utilized by the population
    iv. Information on the extent to which services/items in the proposal are already covered by health plans and which health plans the proposal would impact
    v. Cost considerations regarding the potential of the proposal to increase cost of care as well as its potential to increase enrollee premiums in impacted health plans
    vi. The cost to the state if the proposal is determined to be a mandated benefit under the Affordable Care Act (ACA)
b. As part of these evaluations, Commerce also seeks public feedback on the proposed benefit mandates. This public feedback is summarized and incorporated into the analysis.
c. The following analysis describes the proposed benefit mandate's impact on the health care industry and the population health of Minnesotans.

Evaluation Components

For the purposes of this evaluation, we used the following terms to describe the impact of the proposed mandate:

Public health. The science and practice of protecting and improving the health and well-being of people and their communities. The field of public health includes many disciplines, such as medicine, public policy, biology, sociology, psychology and behavioral sciences, and economics and business.

Economic impact. The general financial impact of a drug, service, or item on the population prescribing or utilizing the drug, service, or item for a particular health condition.

Fiscal impact. The quantifiable cost to the state associated with implementation of the mandated health benefit proposal. The areas of potential fiscal impact that Commerce reviews for are the cost of defrayal of benefit mandates under the ACA, the cost to the State Employee Group Insurance Program (SEGIP), and the cost to other state public programs.

Bill Requirements

House File 4899 is sponsored by Representative Reyer and Representative Youakim and was introduced in the 92nd Legislature (2021–2022) on May 20, 2022.

If enacted, this bill would require coverage for biomarker testing. “Biomarker" refers to a characteristic that is objectively measured and evaluated as an indicator of normal biological processes, pathogenic processes, or pharmacologic responses to a specific therapeutic intervention. Biomarkers include but are not limited to gene mutations and protein expression.[1]

Under the proposed mandate, coverage would be required for biomarker testing to diagnose, treat, manage, and monitor illness or disease when the testing is supported by medical evidence, including but not limited to

- nationally recognized clinical practice guidelines,
- consensus statements,
- labeled indications for a U.S. Food and Drug Administration (FDA)–approved or FDA-cleared test or indicated tests for an FDA-approved drug, and
- Centers for Medicare & Medicaid Services (CMS) national coverage determinations or Medicare Administrative Contractor (MAC) local coverage determinations.

Related Health Conditions

There are many health conditions potentially associated with this mandate, including cancer, Alzheimer's disease, and human immunodeficiency virus (HIV).[1]

The Minnesota-specific statistics of cancer, Alzheimer’s disease, and HIV are as follows:

- An estimated 26,000 new cancer cases are diagnosed in Minnesota each year.[2]
- In 2020, approximately 99,000 people in Minnesota aged 65 and older were reported as living with Alzheimer’s disease.[3]
- In 2021, 298 individuals were newly diagnosed with HIV in Minnesota.[4]

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[1] Haskell, R. (2019, November 13). What is a biomarker? *NursingCenter Blog*. https://www.nursingcenter.com/ncblog/november-2019/biomarker

[2] Minnesota Department of Health. (n.d.). *Data: Minnesota cancer reporting systems cancer statistics and reports* [Cancer fact sheets]. https://www.health.state.mn.us/data/mcrs/data/index.html

[3] Alzheimer’s Association. (n.d.). *Minnesota* [Webpage]. https://www.alz.org/professionals/public-health/state-overview/minnesota

[4] Minnesota Department of Health. (2021). *HIV outbreak response and case counts.* https://www.health.state.mn.us/diseases/hiv/stats/hiv.html#:~:text=In%202021%2C%20298%20people%20were,drugs%20or%20share%20needles%2Fworks

Related State and Federal Laws

This section provides an overview of state and federal laws related to the proposed mandate and any external factors that provide context for the current policy trends related to this topic. The review of current state and federal laws considers how implementation of the proposed mandate may be affected by federal and Minnesota state health care laws and provides examples of similar legislation or policies in other states.

Federal Laws Relevant to the Proposed Mandate

Coverage for lab testing is one of the essential health benefits (EHBs) established in the ACA. However, specific types of lab testing are not explicitly defined, which may lead to gaps in coverage.[5] Medicare has specified coverage of biomarker testing and genetic sequencing for several types of cancer but does not have broader based requirements for coverage of biomarker testing.[6,7] While state Medicaid programs vary in the extent to which they require coverage of biomarker testing, a 2020 report found that about 40% of states provide comprehensive coverage of such testing.[8]

Minnesota State Laws Relevant to the Proposed Mandate

To date, no Minnesota statutes or regulations have addressed biomarker testing.

State Comparison

Four states have passed bills or implemented health care statutes requiring coverage for biomarker testing:

- Arizona House Bill 2144[9] requires health insurance coverage for biomarker testing for the purposes of diagnosis, treatment, management, or monitoring of any medical condition.
- Illinois House Bill 1779 requires state-regulated insurance and managed care plans to cover biomarker testing for the purposes of diagnosis, treatment, management, or monitoring of any medical condition.

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[5] HealthCare.gov. (n.d.). *Health benefits and coverage: What Marketplace health insurance plans cover* [Webpage]. https://www.healthcare.gov/coverage/what-marketplace-plans-cover/

[6] Centers for Medicare & Medicaid Services. (n.d.). *Next generation sequencing (NGS)* [Webpage]. https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?NCDId=372

[7] Centers for Medicare & Medicaid Services. (n.d.). *Genomic sequence analysis panels in the treatment of solid organ neoplasms* [Webpage]. https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=37810

[8] LUNGevity. (2020, March). *State scorecard: State Medicaid coverage policy and impact on lung cancer outcomes.* https://www.lungevity.org/sites/default/files/state-scorecards/LUNGevity-scorecard-030920.pdf

[9] Arizona House Bill 2144, 2022 Fifty-fifth Legislature 2nd Regular (2022). https://legiscan.com/AZ/bill/HB2144/2022. Summary: Health insurance coverage; biomarker testing.

- Louisiana Senate Bill 84[10] (now Act No. 43) passed in June 2021 and was effective on January 1, 2022. Language in the law refers to providing coverage for "genetic testing for various cancer mutations" and not "biomarkers"; it may not apply to any or all biomarker testing, depending on illness.
- Rhode Island Senate Bill 2201[11] requires state-regulated individual and group health insurance plans to cover biomarker testing for the purposes of diagnosis, treatment, management, or monitoring of any medical condition.

Public Comments Summary

To assess the public health, economic, and fiscal impact of HF 4899, Commerce solicited stakeholder engagement on the potential health benefit mandate. The public submitted comments in response to Minnesota's RFI process, which enabled the state to collect information from consumers, health plans, advocacy organizations, and other stakeholders. This process helped Commerce gather opinions, identify special considerations, and secure additional resources to support the evaluation. This section includes a summary of the key themes collected from stakeholders who submitted comments.

Any studies, laws, and other resources identified by stakeholders through public comment were evaluated based on criteria used for the literature scan. Please refer to the Methodology section for analysis of the reviewed literature. Responses to the RFI may not be fully representative of all stakeholders or of the opinions of those impacted by the proposed mandate.

Stakeholder Engagement Analysis

For this proposed mandate, Commerce received eight stakeholder comments. Half of the stakeholders were in favor of the proposed mandate, and the other half expressed no opinion but provided cost estimates and expert information. The types of stakeholders that submitted responses included health care providers and physicians, state and commercial health carriers, and industry experts.

Stakeholders noted that Minnesota is one of 10 states that do not have a local coverage determination for biomarker testing by the Medicare Administrative Contractor.

Commercial health carriers and health care providers who provided RFI responses stated that biomarker testing is not clearly defined in the proposed mandate. Health care providers expressed their belief that access to a wide variety of biomarker testing will reduce the overall costs of patient care by identifying the appropriate treatment for each individual. However, health carriers and

[10] Act 43 Louisiana R.S. 22:1028.3 (2022). https://legis.la.gov/legis/ViewDocument.aspx?d=1230690. Provides for health insurance coverage of genetic testing for various cancer mutations.
[11] Accident and Sickness Insurance Policies: Biomarker Testing Coverage, Rhode Island Senate Bill 2201, 2022 Regular Session (2022). https://legiscan.com/RI/bill/S2201/2022

industry experts mentioned that some tests are more effective than others and that coverage should be limited to tests that are supported by evidence-based, peer-reviewed clinical guidelines.[12] Stakeholders stressed the importance of defining which biomarker tests should be covered by the mandate because there is currently no language in the proposed mandate addressing frequency of testing, the medical conditions to which the mandate would apply, or the appropriateness of specific tests. One stakeholder stated, "There are instances in which whole genome testing—which is referenced in the bill—is appropriate, but other instances in which a specific biomarker test would be more appropriate and cost effective." Stakeholders agreed that if biomarker testing is not clearly defined within the proposed mandate, ineffective biomarker tests could result in unnecessary or ineffective treatments that add costs to patients care.

One stakeholder commented that because the proposed health benefit mandates only apply to fully insured plans, they may have the potential to drive more employer groups to switch to self-insured coverage to avoid potential costs associated with benefit mandates. This stakeholder referenced a source that showed enrollment changes in self-insured and fully insured plans since 2011. This source indicates that, while enrollment has increased for self-insured private health care plans and decreased in fully insured private health care plans, enrollment in public health care plans has also increased. The source does not provide data to indicate whether a causal relationship exists between the state insurance mandates and employer selection of self-insured plans given other variables that may account for changes in enrollment.[13,14]

Stakeholder and MMB feedback noted the following cost estimates related to coverage of self-measured blood pressure devices and related services:

- MMB provided Commerce with SEGIP's estimate of the fiscal impact of the proposed mandate. For FY23, SEGIP's health plan administrators estimate a potential per member per month (PMPM) increased cost of up to $0.15.
- Stakeholders cited a study that estimates if biomarker testing coverage is expanded, the possible range of premium impacts ranged from $0.14 to $0.51 PMPM.[15]

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[12] Stakeholders noted that there are (a) 26 evidence-based, peer-reviewed clinical guidelines that cover 59 gene–drug pairs and (b) expert groups that have established lists of peer-reviewed biomarker tests. The expert groups include the National Comprehensive Cancer Network for oncology biomarker testing, the University of Minnesota pharmacogenomics biomarker testing (PGx) expert group on scientific evidence for clinical guidance on the use of PGx in direct patient care, and the Clinical Pharmacogenetics Implementation Consortium.

[13] Minnesota Department of Health. (2022, July). *Trends and variation in health insurance coverage* (Chartbook Section 2). https://www.health.state.mn.us/data/economics/chartbook/docs/section2.pdf

[14] The federal Employee Retirement Income Security Act of 1974 (ERISA) preempts state laws that "relate to" a covered employee benefit plan. Under ERISA, a state cannot deem a self-funded employee benefit plan as insurance for the purpose of imposing state regulation. Therefore, self-funded (or self-insured) plans may be exempt from abiding by a state-imposed health benefit mandate.

[15] Dieguez, G., & Carloto, J. (2022, February). *The landscape of biomarker testing coverage in the United States*. Milliman. https://www.milliman.com/-/media/milliman/pdfs/2022-articles/2-16-22_the_landscape_of_biomarker_testing_coverage_in_the_us.ashx

- One commercial health carrier estimated that if the utilization of biomarker testing were to double with expanded coverage, then paid claims could increase to $0.25 PMPM from $0.10 PMPM.

Cost estimates shared in RFI responses may reflect different methodologies, data sources, and assumptions than those used in the actuarial analysis for this evaluation. Therefore, stakeholders' results may or may not reflect generalizable estimates for the mandate.

Evaluation of Mandated Health Benefit Proposal

The methodology for relevant sections of these evaluations is described in the corresponding evaluation below and consisted of a three-pronged approach:

- Medical/scientific review
- Actuarial analysis to assess economic impact
- Defrayal analysis to assess fiscal impact

Methodology for Analysis of Reviewed Literature

This evaluation used critical review of research databases to identify scientific, medical, and regulatory sources relevant to the mandate. The literature scan utilized

I. key scientific, medical, and regulatory terms that emerged from the initial review of the proposed mandate;
II. additional key terms that were identified and reviewed by AIR's technical and subject matter experts, Commerce, and MDH; and
III. additional terms and research questions following public comment and stakeholder engagement interviews.

The key terms guided the search for relevant literature in PubMed and the National Bureau of Economic Research (NBER). PubMed was used to identify relevant biomedical literature and NBER to identify relevant literature that might address the potential public health, economic, and fiscal impacts of the mandate. The inclusion factors prioritized peer-reviewed literature and independently conducted research on any articles or databases identified through public comment. In addition, criteria included publication within the last 10 years, relevance to the proposed health benefit mandate, generalizability of the findings, and quality of the research, as guided by the Joanna Briggs Institute Clinical Appraisal Tools. The analysis included identified key themes and shared patterns related to the medical, economic, or legal impact of the proposed health benefit mandate.

Public Health Impact

The use of biomarker testing is growing and can guide clinical decisions for individuals at increased risk for disease, including decisions about screening frequency and specific treatments.[16] For example, biomarker testing can play an important role in diagnosis and treatment decisions for conditions like cystic fibrosis and lung cancer.[17] Lung cancer represents 25% of all cancer deaths, but targeted therapies based on biomarker testing have been associated with improved clinical outcomes.[18] Evidence suggests that biomarker testing can optimize treatment by using genetic profiles to assess the risk potentials or efficacy of certain drugs based on individual biomarkers. Biomarker testing may reduce adverse outcomes and improve provider drug selection.[19] The Centers for Disease Control and Prevention (CDC) has released resources for the 50 genomic/biomarker tests that have sufficient clinical evidence to be used in clinical decision-making.[20]

Despite this evidence, there is variation in insurance coverage for biomarker testing. More specifically, coverage can range from single-gene to multi-gene biomarker testing. Single-gene testing is more commonly covered than multi-gene testing, but variation exists for each type of testing. The variation in coverage is not always aligned with clinical practice guidelines.[18,20] While some of the variation in coverage is due to the limited evidence base, such as for multi-gene therapy, coverage still varies even when there is consensus across clinical guidelines.[21]

While differences between insurance types (Medicaid vs. commercial) have been correlated with clinical outcomes and health disparities in lung cancer, data are limited on whether insurance coverage of biomarker testing itself is linked to reductions in health disparities and improved clinical outcomes. In one study, Medicaid beneficiaries who were not provided biomarker testing had a 27% increased risk of mortality.[18] However, these results may be confounded by population factors and other variables associated with clinical presentation. While there is some association between the level of insurance coverage and the use of biomarker testing, the evidence is less concrete than for other

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[16] Mansur, A., Zhang, F., & Lu, C. Y. (2022). Genetic testing and/or counseling for colorectal cancer by health insurance type. *Journal of Personalized Medicine*, *12*(7), 1146. https://doi.org/10.3390/jpm12071146

[17] Wu, A. C., Kiley, J. P., Noel, P. J., Amur, S., Burchard, E. G., Clancy, J. P., Galanter, J., Inada, M., Jones, T. K., Kropski, J. A., Loyd, J. E., Nogee, L. M., Raby, B. A., Rogers, A. J., Schwartz, D. A., Sin, D. D., Spira, A., Weiss, S. T., Young, L. R., & Himes, B. E. (2018). Current status and future opportunities in lung precision medicine research with a focus on biomarkers (American Thoracic Society/National Heart, Lung, and Blood Institute research statement). *American Journal of Respiratory and Critical Care Medicine*, *198*(12), e116–e136. https://doi.org/10.1164/rccm.201810-1895st

[18] Gross, C. P., Meyer, C. S., Ogale, S., Kent, M., & Wong, W. B. (2022). Associations between Medicaid insurance, biomarker testing, and outcomes in patients with advanced NSCLC. *Journal of the National Comprehensive Cancer Network*, *20*(5) 479–487. https://doi.org/10.6004/jnccn.2021.7083

[19] Dalton, R., Brown, J. D., & Duarte, J. D. (2021). Patients with geographic barriers to health care access are prescribed a higher proportion of drugs with pharmacogenetic testing guidelines. *Clinical and Translational Science*, *14*(5), 1841–1852. https://doi.org/10.1111/cts.13032

[20] Lu, C., Loomer, S., Ceccarelli, R., Mazor, K., Sabin, J., Clayton, E., Ginsburg, G., & Wu, A. (2018). Insurance coverage policies for pharmacogenomic and multi-gene testing for cancer. *Journal of Personalized Medicine*, *8*(2), 19. https://doi.org/10.3390/jpm8020019

[21] There is consensus in favor of single-gene testing, but those concerned with the clinical utility of multi-gene testing recognize the need for additional research and clinical practice guidelines.

socioeconomic factors. One study indicated that biomarker testing may play a role in reducing disparities associated with race/ethnicity and access to care because biomarker testing may reduce the number of visits required for treatment.[22]

While primary care providers and non-genetics specialists have expressed uncertainty regarding their ability to interpret and incorporate genetic results into clinical practice, early evidence indicates that providers have been implementing these tests in the clinical environment. This may be important in supporting the scalability and benefit of biomarker testing to inform diagnosis and treatment decisions.[23] Experts acknowledge that additional guidelines and research are needed to aid in further standardizing biomarker testing and integrating it into diagnosis and treatment decisions.[24]

Economic Impact

Evidence on the cost-effectiveness of biomarker tests included in clinical practice guidelines is rapidly evolving as more molecular tests are released, and the growth of these tests could decrease costs and lead to more efficient tests. Despite reductions in cost and growing evidence on the effectiveness of biomarker testing, cost continues to be a barrier to the adoption of biomarker testing in clinical practice.[25]

There are data to suggest that medically necessary biomarker testing may be cost-effective and that cost-effectiveness may vary by biomarker test, the timing of testing, and other variables. For instance, proactive testing (testing prior to indicated use) may result in reduced downstream costs of care compared to reactive testing (testing once a suspected need has been established). New evidence on the clinical benefits of biomarker testing and its cost-effectiveness has been used to support some Medicare coverage determinations.[23]

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[22] Dalton, R., Brown, J. D., & Duarte, J. D. (2021). Patients with geographic barriers to health care access are prescribed a higher proportion of drugs with pharmacogenetic testing guidelines. *Clinical and Translational Science*, *14*(5), 1841–1852. https://doi.org/10.1111/cts.13032

[23] Lemke, A. A., Amendola, L. M., Kuchta, K., Dunnenberger, H. M., Thompson, J., Johnson, C., Ilbawi, N., Oshman, L., & Hulick, P. J. (2020). Primary care physician experiences with integrated population-scale genetic testing: A mixed-methods assessment. *Journal of Personalized Medicine*, *10*(4), 165. https://doi.org/10.3390/jpm10040165

[24] Wu, A. C., Kiley, J. P., Noel, P. J., Amur, S., Burchard, E. G., Clancy, J. P., Galanter, J., Inada, M., Jones, T. K., Kropski, J. A., Loyd, J. E., Nogee, L. M., Raby, B. A., Rogers, A. J., Schwartz, D. A., Sin, D. D., Spira, A., Weiss, S. T., Young, L. R., & Himes, B. E. (2018). Current status and future opportunities in lung precision medicine research with a focus on biomarkers (American Thoracic Society/National Heart, Lung, and Blood Institute research statement). *American Journal of Respiratory and Critical Care Medicine*, *198*(12), e116–e136. https://doi.org/10.1164/rccm.201810-1895st

[25] Morris, S. A., Alsaidi, A. T., Verbyla, A., Cruz, A., Macfarlane, C., Bauer, J., & Patel, J. N. (2022). Cost effectiveness of pharmacogenetic testing for drugs with Clinical Pharmacogenetics Implementation Consortium (CPIC) guidelines: A systematic review. *Clinical Pharmacology & Therapeutics*, *112*(6), 1318–1328. https://doi.org/10.1002/cpt.2754

However, other research shows that there is still limited evidence regarding the cost-effectiveness of biomarker testing.[26,27] Because understanding of the use of biomarker testing is evolving, particularly among primary care providers and other nonspecialists, it can lead to unnecessary costs due to provider error in test interpretation and subsequent screening, referral, or treatment decision-making.[27] However, this was not a frequently cited concern in most studies on biomarker testing that were reviewed.

Limitations

Most studies focusing on the impact of biomarker testing coverage on public health evaluated factors associated with insurance status rather than variations in specific coverage. Given the heterogeneity of clinical conditions for which biomarker testing is used, the wide range of biomarkers available, and various levels of evidence for biomarker tests, it is difficult to make general statements about the extent to which the literature supports the proposed mandate. The reviewed cost-effectiveness studies were disease specific or biomarker test specific and not generalizable.

Actuarial Analysis[28]

This actuarial analysis includes an analysis of the current prevalence of qualifying diagnoses, an analysis of cost and beneficiary cost-sharing, and a projection of the potential costs of expanding coverage. There is additional discussion of potential long-term medical savings associated with expanded coverage.

Assumptions and Approach

MDH provided ARC with tabulations from Minnesota's All-Payer Claims Database (APCD) for 2017–2019 that included specified biomarker test services. According to MDH, APCD includes approximately 40% of the total commercial market in Minnesota. These tabulations served as a snapshot of current prevalence and costs.

Beneficiaries were identified as having biomarker testing if they had a claim with one of the Current Procedural Terminology (CPT) codes listed in Appendix C. Code 80322 was redacted for all years because it pertained to less than 11 individuals, so it was excluded from the projections. Code 81490 was redacted for 2019, so as a proxy a weighted average of 2017 and 2018 numbers was included, adjusted to represent 10 members and trended to 2019. Additionally, some codes indicate biomarker

[26] Montanez, K., Berninger, T., Willis, M., Harding, A., & Lutgendorf, M. A. (2020). Genetic testing costs and compliance with clinical best practices. *Journal of Genetic Counseling*, *29*(6), 1186–1191. https://doi.org/10.1002/jgc4.1285

[27] Wu, A. C., Kiley, J. P., Noel, P. J., Amur, S., Burchard, E. G., Clancy, J. P., Galanter, J., Inada, M., Jones, T. K., Kropski, J. A., Loyd, J. E., Nogee, L. M., Raby, B. A., Rogers, A. J., Schwartz, D. A., Sin, D. D., Spira, A., Weiss, S. T., Young, L. R., & Himes, B. E. (2018). Current status and future opportunities in lung precision medicine research with a focus on biomarkers (American Thoracic Society/National Heart, Lung, and Blood Institute research statement). *American Journal of Respiratory and Critical Care Medicine*, *198*(12), e116–e136. https://doi.org/10.1164/rccm.201810-1895st

[28] Michael Sandler and Anthony Simms are actuaries for Actuarial Research Corporation (ARC). They are members of the American Academy of Actuaries and meet the qualification standards of the American Academy of Actuaries to render the actuarial opinions contained herein.

testing but were not found in the data. The reason, according to MDH, is that most were added in 2020 or later. Codes that were excluded from the projections are listed in Appendix C.

The overall Minnesota population projections for 2024–2033 are based on the figures published by the Minnesota State Demographic Center and on the historical non-public health insurance coverage levels from Minnesota Public Health Data Access. The analysis assumed that 65% of the total state population would be included in the non-public insured population.

A 2022 white paper[29] discusses a study of administrative claims data from 2020 aimed at quantifying the impact of expanded biomarker testing coverage on different markets, including the commercial market. Self-insured large group plans were split into quartiles by tests per 1,000 individuals, and these percentiles were used to represent coverage levels and also as benchmarks in this analysis. Table 1 contains these quartiles as well the 2024 baseline estimate of testing per 1,000 individuals in the Minnesota non-public health insurance population.

Costs were projected for 2024–2033 using Physician and Clinical projection factors derived from private health insurance trends from the National Health Expenditure data.

Table 1. Assumed Percentiles of Biomarker Testing per 1,000 Individuals Used in HF 4899 Analysis[36]

Percentile	Biomarker testing frequency per 1,000 Individuals
90th Percentile	39.4
75th Percentile	32.7
50th Percentile	25.9
25th Percentile	14.4
MN NPHI estimated 2024 tests per 1,000	1.3
10th Percentile	1.0

Results

Table 2 shows projected prevalence and costs for biomarker testing under the current law based on historical data. PMPM cost-sharing begins at $3.11 in Year 1 and increases to $4.51 in the 10th and final year of the projection. Total non-public insured population PMPM expenditures attributable to biomarker testing begin at less than a penny in Year 1 and increase to around 1.4 cents by Year 10.

Tables 3–5 show potential projected changes in prevalence, expenditures, cost-sharing, and net effect on total non-public insured PMPM for biomarker testing under the mandate. Low-, moderate-, and high-coverage scenarios—with tests per 1,000 individuals rising to the 25th, 50th, and 75th percentiles, respectively (see Table 1)—are shown.

[29] Dieguez, G., Ferro, C., & Rotter, D. (2018, October). *The cost burden of cancer care: A longitudinal analysis of commercially insured patients diagnosed with blood cancer*. Milliman. https://www.lls.org/sites/default/files/Milliman%20study%20cost%20burden%20of%20blood%20cancer%20care.pdf

Table 2. Projected Expenditures Related to Biomarker Testing Coverage Requirements: Current Law[30]

	Total MN pop	Non-public insured pop	Biomarker testing pop	Plan paid	Cost-sharing	Cost-sharing PMPM for biomarker testing beneficiaries	Total non-public insured pop PMPM
2024	5,834,936	3,792,708	2,153	$414,617.87	$80,380.93	$3.11	$0.009
2025	5,870,258	3,815,668	2,166	$438,871.74	$85,051.25	$3.27	$0.010
2026	5,904,930	3,838,205	2,179	$462,697.07	$89,500.42	$3.42	$0.010
2027	5,938,797	3,860,218	2,191	$486,247.95	$93,783.16	$3.57	$0.010
2028	5,971,790	3,881,664	2,203	$510,298.13	$98,110.93	$3.71	$0.011
2029	6,003,838	3,902,495	2,215	$535,705.83	$102,566.86	$3.86	$0.011
2030	6,034,892	3,922,680	2,227	$561,423.97	$107,041.58	$4.01	$0.012
2031	6,064,909	3,942,191	2,238	$589,041.96	$111,876.95	$4.17	$0.012
2032	6,093,866	3,961,013	2,249	$617,895.94	$116,907.55	$4.33	$0.013
2033	6,121,752	3,979,139	2,259	$648,035.32	$122,140.23	$4.51	$0.014

[30] The state health benefit mandates only apply to non-public, fully insured large, small, and individual plans and to SEGIP, except where explicitly indicated. However, the actuarial analysis is based on gross expenditures for all non-public insurance in Minnesota. Although the analysis was not limited to data only for fully insured plans and SEGIP, this does not affect the accuracy of the PMPM estimates. Using all non-public claims improves the robustness and accuracy of the PMPM estimates because the analyses rely on a larger, more representative set of data.

Table 3. Projected Expenditures Related to Biomarker Testing: Low-Coverage Scenario[31]

	Biomarker testing pop	Plan paid	Cost-sharing	Total non-public insured pop PMPM	Non-public insured pop PMPM net effect
2024	23,577	$4,540,402.94	$880,236.57	$0.10	$0.09
2025	23,720	$4,806,002.53	$931,380.35	$0.10	$0.10
2026	23,860	$5,066,909.26	$980,102.45	$0.11	$0.10
2027	23,997	$5,324,810.61	$1,027,001.90	$0.11	$0.10
2028	24,130	$5,588,179.67	$1,074,394.51	$0.12	$0.11
2029	24,260	$5,866,414.61	$1,123,190.52	$0.13	$0.11
2030	24,385	$6,148,049.13	$1,172,192.33	$0.13	$0.12
2031	24,506	$6,450,488.64	$1,225,143.62	$0.14	$0.12
2032	24,623	$6,766,463.20	$1,280,232.81	$0.14	$0.13
2033	24,736	$7,096,513.85	$1,337,534.91	$0.15	$0.14

[31] The state health benefit mandates only apply to non-public, fully insured large, small, and individual plans and to SEGIP, except where explicitly indicated. However, the actuarial analysis is based on gross expenditures for all non-public insurance in Minnesota. Although the analysis was not limited to data only for fully insured plans and SEGIP, this does not affect the accuracy of the PMPM estimates. Using all non-public claims improves the robustness and accuracy of the PMPM estimates because the analyses rely on a larger, more representative set of data.

Table 4. Projected Expenditures Related to Biomarker Testing: Moderate-Coverage Scenario[32]

	Biomarker testing pop	Plan paid	Cost-sharing	Total non-public insured pop PMPM	Non-public insured pop PMPM net effect
2024	42,406	$8,166,419.18	$1,583,203.27	$0.18	$0.17
2025	42,663	$8,644,129.54	$1,675,191.05	$0.19	$0.18
2026	42,915	$9,113,399.29	$1,762,823.16	$0.20	$0.19
2027	43,161	$9,577,263.54	$1,847,177.03	$0.21	$0.20
2028	43,401	$10,050,962.04	$1,932,417.90	$0.22	$0.20
2029	43,634	$10,551,398.50	$2,020,182.94	$0.23	$0.21
2030	43,859	$11,057,949.48	$2,108,318.16	$0.23	$0.22
2031	44,077	$11,601,920.53	$2,203,556.93	$0.25	$0.23
2032	44,288	$12,170,235.90	$2,302,640.96	$0.26	$0.24
2033	44,490	$12,763,868.66	$2,405,705.14	$0.27	$0.25

[32] The state health benefit mandates only apply to non-public, fully insured large, small, and individual plans and to SEGIP, except where explicitly indicated. However, the actuarial analysis is based on gross expenditures for all non-public insurance in Minnesota. Although the analysis was not limited to data only for fully insured plans and SEGIP, this does not affect the accuracy of the PMPM estimates. Using all non-public claims improves the robustness and accuracy of the PMPM estimates because the analyses rely on a larger, more representative set of data.

Table 5. Projected Expenditures Related to Biomarker Testing: High-Coverage Scenario[33]

	Biomarker testing pop	Plan paid	Cost-sharing	Total non-public insured pop PMPM	Non-public insured pop PMPM net effect
2024	53,540	$10,310,498.35	$1,998,870.54	$0.23	$0.22
2025	53,864	$10,913,630.74	$2,115,009.55	$0.24	$0.23
2026	54,182	$11,506,106.44	$2,225,649.32	$0.25	$0.24
2027	54,493	$12,091,757.44	$2,332,150.15	$0.26	$0.25
2028	54,795	$12,689,824.66	$2,439,770.87	$0.27	$0.26
2029	55,089	$13,321,649.84	$2,550,578.47	$0.28	$0.27
2030	55,374	$13,961,194.90	$2,661,853.43	$0.30	$0.28
2031	55,650	$14,647,984.61	$2,782,096.97	$0.31	$0.30
2032	55,915	$15,365,510.19	$2,907,195.34	$0.32	$0.31
2033	56,171	$16,115,000.20	$3,037,318.85	$0.34	$0.32

[33] The state health benefit mandates only apply to non-public, fully insured large, small, and individual plans and to SEGIP, except where explicitly indicated. However, the actuarial analysis is based on gross expenditures for all non-public insurance in Minnesota. Although the analysis was not limited to data only for fully insured plans and SEGIP, this does not affect the accuracy of the PMPM estimates. Using all non-public claims improves the robustness and accuracy of the PMPM estimates because the analyses rely on a larger, more representative set of data.

Depending on the realized level of mandated coverage and utilization, total non-public insured population PMPM expenditures are projected to increase between $0.09 and $0.22 in Year 1 and between $0.14 and $0.32 in Year 10. On average, an increase of about 1.2 tests per 1,000 individuals would result in a net increase of $0.01 in PMPM premiums.

A comprehensive actuarial analysis and modeling of projected downstream medical savings resulting from increased coverage of biomarker testing was beyond the scope of this project. A literature review was conducted to identify potential areas and levels of savings and possible avenues of additional analysis:

- A 2021 study compared the cost of biomarker testing with the cost of whole-genome sequencing in patients with non-small cell lung cancer (NSCLC). The study included 102 stage IV NSCLC patients who received biomarker testing in 2017 or 2018 at a comprehensive cancer center in the Netherlands. The study concluded that replacing current testing with whole-genome sequencing would have led to cost savings in only two patients (2%) at the current biomarker testing cost level.[34]
- A 2021 article discussing the economics of biomarker testing mentioned that biomarker testing is significantly cheaper than many newly approved cancer drugs and that it can save on drug expenditures by preempting the use of these drugs in patients for whom such treatment would be ineffective. For example, a biomarker test can detect certain instances of lung or colorectal cancers that are resistant to available treatments.[35]
- A 2019 study simulated cases of diabetes to compare the costs of biomarker screening followed by genetic testing for maturity-onset diabetes of the young versus usual care over a 30-year period. The study found that biomarker screening and genetic testing decreased costs by an average of $191 per simulated patient relative to usual care over the 30-year period and that the savings increased to $735 if cascading genetic testing was used after biomarker screening. This suggests that the strategy yields some savings.[36]

[34] van de Ven, M., Koffijberg, H., Retél, V., Monkhorst, K., Smit, E., van Harten, W., & IJzerman, M. (2019, October). Real-world utilization of biomarker testing for patients with advanced non–small cell lung cancer in a tertiary referral center and referring hospitals. *Journal of Molecular Diagnostics, 23*(4), 484–494. https://www.jmdjournal.org/article/S1525-1578(21)00005-2/fulltext

[35] OncoDNA. (2021, March 24). *The economics of comprehensive biomarker testing in cancer* [Webpage]. https://www.oncodna.com/en/company/activity/news-list/comprehensive-biomarker-testing-cancer-drug-costs/

[36] Goodsmith, M., Skandari, M. R., Huang, E. S., & Naylor, R. N. (2019). The impact of biomarker screening and cascade genetic testing on the cost-effectiveness of MODY genetic testing. *Diabetes Care, 42,* 2247–2255. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6868460/

- A 2019 article cited a systematic literature review and economic analysis conducted for the United Kingdom's National Health Service that suggested that the Triage and Elecsys biomarker test for pregnant women could save money if added to standard testing for preeclampsia.[37]
- A 2020 study used a decision analytic model to assess the cost-effectiveness of PrismRA testing for rheumatoid arthritis patients who are unlikely to respond to anti-tumor necrosis factor therapies. The study found that PrismRA testing decreased overall costs by 5% and costs due to ineffective treatment by 22% for the first 12 months after initiating biologic therapy, though the costs of the testing itself were not taken into account.[38]
- A 2020 study assessed the effectiveness of blood-based biomarker (BBBM) testing in identifying eligibility for disease-modifying treatment (DMT) for Alzheimer's to lower wait times and costs. The study modeled BBBM use in three of four scenarios and found that BBBM with a cognitive test would yield 120,000 additional correct identifications of DMT per year, reduce annual costs by $400 to $700 million, and work through wait lists in 3 years.[39]

Data Sources

- Minnesota state population projections are from *Long-Term Population Projections for Minnesota*, published by the Minnesota State Demographic Center.[40]
- Minnesota non-public health insurance coverage levels are from Minnesota Public Health Data Access.[41]
- Trends and projection factors are derived from National Health Expenditure data compiled by the CMS.[42]
- MDH tabulations of data from Minnesota's All-Payer Claims Database for 2017–2019 were used for the estimation of the diagnosis prevalence of select rare diseases associated with biomarker testing.

[37] Schlembach, D., Hund, M., Wolf, C., & Vatish, M. (2019, July). Diagnostic utility of angiogenic biomarkers in pregnant women with suspected preeclampsia: A health economics review. *Pregnancy Hypertension,* 17, 28–35. https://www.sciencedirect.com/science/article/pii/S2210778918307670

[38] Bergman, M., Kivitz, A. G., Pappas, D. A., Kremer, J. M., Zhang, L., Jeter, A., & Withers, J. B. (2020). Clinical utility and cost savings in predicting inadequate response to anti-TNF therapies in rheumatoid arthritis. *Rheumatology and Therapy, 7*, 775–792. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7695768/

[39] Mattke, S., Cho, S. K., Bittner, T., Hlávka, J., & Hanson, M. (2020). Blood-based biomarkers for Alzheimer's pathology and the diagnostic process for a disease-modifying treatment: Projecting the impact on the cost and wait times. *Alzheimer's Disease and Dementia,* 12(1), e12081. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7434228/

[40] https://mn.gov/admin/assets/Long-Term-Population-Projections-for-Minnesota-DATA-feb2021_tcm36-469204.xlsx

[41] https://data.web.health.state.mn.us/insurance_basic

[42] https://www.cms.gov/files/zip/nhe-historical-and-projections-data.zip

Fiscal Impact

The potential fiscal impact of this legislation for the state includes the estimated cost to SEGIP as assessed by SEGIP in consultation with health plan administrators, the cost of defrayal of benefit mandates as understood under the ACA, and the estimated cost to public programs.

- The SEGIP estimated the partial fiscal impact of this legislation would be $116,100 in partial Fiscal Year 2023 (FY23) and $243,810 in FY24.
- The defrayal cost assessed by Commerce under the ACA is estimated to be up to $2,594,000 in the first year.
- There is no estimated fiscal impact for public programs.

Fiscal Impact Estimate for SEGIP

MMB provided Commerce with SEGIP's fiscal impact analysis, which is based on current allowable amounts for members who have utilized biomarker testing, predicted increase of utilization of biomarker tests, and plan coverage of claims formerly rejected by SEGIP. The program estimated the partial fiscal impact of this legislation would be $116,100 in FY23, $243,810 in FY24, and $256,000 in FY25.

ACA Mandate Impact and Analysis

The ACA defined 10 EHBs that must be included in non-grandfathered plans in the individual and small-group markets. Pursuant to section 1311(d)(3)(b) of the ACA, states may require qualified health plan issuers to cover benefits in addition to the 10 EHBs but must defray the costs of requiring issuers to cover such benefits by making payments either to individual enrollees or directly to qualified health plan issuers on behalf of the enrollees.

Any state-required benefits enacted after December 31, 2011, other than for purposes of compliance with federal requirements, would be considered in addition to EHBs even if embedded in the state's selected benchmark plan.[43] States must identify the state-required benefits that are in addition to EHBs, and qualified health plan issuers must quantify the cost attributable to each additional required benefit based on an analysis performed in accordance with generally accepted actuarial principles and methodologies conducted by a member of the American Academy of Actuaries and must report this to the state.[44]

Commerce has determined that HF 4899 would likely constitute a benefit mandate as defined under the ACA, as biomarker testing is not currently covered broadly under the state's benchmark plan. The amount required to be defrayed by the state is projected to be up to $2,594,000 in the first year.

[43] See 45 CFR §155.170(a)(2).
[44] See 45 CFR §155.170(a)(3) and §155.170(c).

Commerce has made this estimate based on a number of data sources previously cited. Data indicate that approximately 1.2% of enrollees in individual plans nationally may receive some sort of biomarker testing. However, since it is not possible to have a precise indicator of the number of QHP enrollees receiving biomarker testing, Commerce has increased this to 2% to create a safe harbor for determining potential defrayal costs.

The cost of biomarker testing ranges between approximately $200 and $1,800.[45] Commerce utilized QHP enrollment as of October 2022, determined the proportion that would likely receive biomarker testing, and multiplied that number by the low and high prices per test. These amounts were then adjusted according to the average actuarial value based on QHP enrollment through MNsure (approximately 68%) to reflect the insurers' cost. Commerce utilized higher than average figures in order to determine an upper threshold to the potential defrayal amount. Based on this estimate, the cost of defrayal for biomarker testing may range from $432,000 to $2,594,000 in the first year if HF 4899 were enacted.

Fiscal Impact for Public Programs

There is no estimated cost for public programs, as the state insurance mandate only applies to non-public, fully insured small, large, and individual plans and to SEGIP, unless explicitly stated. As indicated by the mandate, Minnesota's Medical Assistance has existing biomarker coverage (see Appendix A).

[45] van de Ven, M., Koffijberg, H., Retél, V., Monkhorst, K., Smit, E., van Harten, W., & IJzerman, M. (2019, October). Real-world utilization of biomarker testing for patients with advanced non–small cell lung cancer in a tertiary referral center and referring hospitals. *Journal of Molecular Diagnostics, 23*(4), 484–494. https://www.jmdjournal.org/article/S1525-1578(21)00005-2/fulltext

Appendix A. Bill Text

A bill for an act relating to insurance; requiring health plans to provide coverage for biomarker testing; amending Minn. Stat. 2020 § 256B.0625, by adding a subdivision; proposing coding for new law in Minn. Stat. chapter 62Q.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MINNESOTA:

Section 1.

[62Q.473] BIOMARKER TESTING.

Subdivision 1.

Definitions.

(a) For the purposes of this section, the terms defined in this subdivision have the meanings given.

(b) "Biomarker" means a characteristic that is objectively measured and evaluated as an indicator of normal biological processes, pathogenic processes, or pharmacologic responses to a specific therapeutic intervention. Biomarkers include but are not limited to gene mutations or protein expression.

(c) "Biomarker testing" means the analysis of an individual's tissue, blood, or other biospecimen for the presence of a biomarker. Biomarker testing includes but is not limited to single-analyst tests, multiplex panel tests, and whole genome sequencing.

(d) "Consensus statement" means a statement developed by an independent, multidisciplinary panel of experts (1) using a transparent methodology and reporting structure, and (2) with a conflict of interest policy. A statement must be applicable to specific clinical circumstances and based on the best available evidence.

(e) "Nationally recognized clinical practice guideline" means an evidence-based clinical practice guideline developed by an independent organization or medical professional society (1) using a transparent methodology and reporting structure, and (2) with a conflict of interest policy. A clinical practice guideline establishes a standard of care informed by a systematic review of evidence and an assessment of the benefits and costs of alternative care options, and includes recommendations to optimize patient care.

Subd. 2.

Biomarker testing; coverage required.

(a) A health plan company must provide coverage for biomarker testing to diagnose, treat, manage, and monitor illness or disease.

(b) A health plan company is only required to provide coverage of biomarker testing when the test is supported by medical evidence, including but not limited to:

(1) nationally recognized clinical practice guidelines;

(2) consensus statements;

(3) labeled indications for a United States Food and Drug Administration (FDA)-approved or FDA-cleared test, or indicated tests for an FDA-approved drug; or

(4) Centers for Medicare and Medicaid Services national coverage determinations or Medicare Administrative Contractor local coverage determinations.

(c) Coverage under this section must be provided in a manner that limits disruption of care, including the need for multiple biopsies or biospecimen samples.

EFFECTIVE DATE.

This section is effective January 1, 2023, and applies to health plans offered, issued, or renewed on or after that date.

Sec. 2.

Minn. Stat. 2020 § 256B.0625, is amended by adding a subdivision to read:

Subd. 68.

Biomarker testing.

Medical assistance covers biomarker testing to diagnose, treat, manage, and monitor illness or disease. Medical assistance coverage must meet the requirements that would otherwise apply to a health plan company under section 62Q.473.

EFFECTIVE DATE.

This section is effective January 1, 2023, or upon federal approval, whichever is later.

Appendix B. Key Search Terms for Literature Scan

Alzheimer's disease

Biomarker testing

Cancer

Chronic kidney disease

Clinical practice guidelines

Consensus statement

Gene mutations

Genetic testing

Genome sequencing

Genomic molecular testing

Human immunodeficiency virus (HIV)

Molecular profiling

Protein expression

Tumor testing

Appendix C. Associated Codes

Included CPT Code(s):

Biomarker Associated Code(s)	
Name	**Code(s)**
Definitive Drug Testing Procedures	80321, 80322
Multianalyte Assays With Algorithmic Analyses	81490
Chemistry Procedures	82373
Qualitative or Semiquantitative Immunoassays	86352

Excluded CPT Codes:

Biomarker Excluded Code(s)	
Name	**Code(s)**
Multivariate Index Assay, 2nd Generation (MIA2G)	0003U
NPDX ASD ADM Panel I Test	0063U
BBDRisk Dx	0067U
NPDX ASD and Central Carbon Energy Metabolism Test	0263U
HART CADhs	0308U
HART CVE	0309U
HART KD	0310U
PancreaSeq Genomic Classifier	0313U
NPDX ASD Test Panel III	0322U
Multianalyte Assay	0015M
Magnetic Resonance Spectroscopy Imaging	0609T, 0610T, 0611T, 0612T,